510(k) Summary

as required by 21 CFR Part 807.87(h)

JUN - 8 2011

Identification of the Submitter

Establishment:	Siemens Medical Solutions USA, Inc. 51 Valley Stream Parkway Mail Code G01 Malvern, PA 19355, USA Establishment Registration Number 2240869
Manufacturer:	Siemens AG Henkestrasse 127 D-91052 Erlangen, Germany Establishement Registration Number 8010024
Contact Person:	Alaine Medio, RAC PET and PCS Regulatory Projects Manager Siemens Medical Solutions USA, Inc. 810 Innovation Drive Knoxville, TN 37934 Alaine.medio@siemens.com Phone (865) 218-2703 FAX (865)218-3019
Date of Submission:	November 19, 2010

Identification of the product

Device Proprietary Name:	Biograph mMR
Common Name:	Magnetic Resonance Diagnostic Device Positron Emission Tomography (PET) System
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200
Product Code:	OUO
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
MAGNETOM Verio	Siemens AG	K072237
MR B17 Software Update	Siemens AG	K082427
Biograph mCT·X and mCT·S (Biograph HD)	Siemens Medical Solutions USA, Inc.	K101550 and K081453

Device Description:

The Biograph mMR systems are combined Magnetic Resonance Diagnostic Devices (MRDD) and Positron Emission Tomography (PET) scanners. These systems are designed for whole body oncology, neurology and cardiology examinations. The Biograph mMR systems provide registration and fusion of high-resolution metabolic and anatomic information from the two major components of each system (MR and PET). Additional components of the system include: a patient bed and both, the acquisition and processing, workstations with associated software.

The Biograph mMR includes a 3T superconducting magnet, gradient coil, body coil and local RF coils based on those of the predicate MAGNETOM Verio 3T system. The Biograph mMR PET detectors have been updated from those of the predicate Biograph mCT to allow them to be integrated into the bore of the MR. This allows for simultaneous, precisely aligned whole body MR and PET acquisition.

Biograph mMR software is based on a combination of MAGNETOM Verio with B17 software, and Biograph mCT software. It is used for patient management, data management, scan control, image reconstruction and image archival and evaluation. All images conform to DICOM imaging format requirements.

The Biograph mMR system, the subject of this application, is substantially equivalent to the commercially available devices above with modifications made to integrate the two modalities together into a whole-body system.

Safety and Effectiveness:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions, USA Inc. and Siemens AG adhere to recognized and established industry standards such as IEC 60601-1 series to minimize electrical and mechanical hazards.

The Biograph mMR conforms to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as required by the respective MR and PET FDA Guidance Documents.

Indications for Use:

The Siemens MR-PET system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information, acquired simultaneously and isocentrically. The combined system maintains independent functionality of the MR and PET devices, allowing for single modality MR and / or PET imaging.

These systems are intended to be utilized by appropriately trained health care professionals to aid in the detection, localization, and diagnosis of diseases and disorders.

The MR is intended to produce transverse, sagittal, coronal and oblique cross-sectional MR-images, spectroscopic images and/or spectra, and displays the internal structure and/or function of the human body. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, approved contrast agents may be used, as described in their labeling. This system may also be used for imaging during interventional procedures when performed with MR compatible devices, such as MR-safe biopsy needles.

The PET images and measures the distribution of PET radiopharmaceuticals in humans to aid the physician in determining various metabolic (molecular) and physiologic functions within the human body for evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer.

The combined system utilizes the MR for radiation-free attenuation correction maps for PET studies. The system provides inherent anatomical reference for the fused PET and MR images due to precisely aligned MR and PET image coordinate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Alaine Medio, RAC
PET and PCS Regulatory Projects Manager
Siemens Medical Solutions USA, Inc.
810 Innovation Drive
KNOXVILLE TN 37932-2751

JUN - 8 2011

Re: K103429
Trade/Device Name: Biograph mMR
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: OUO
Dated: April 19, 2011
Received: April 20, 2011

Dear Ms. Medio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K103429

INDICATIONS FOR USE

510(k) Number (if known):

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Prescription Use___X___ AND/OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103429